

Routine Maintenance Procedure

To maintain your System 83 Plus™ in optimal condition, routine maintenance procedures must be performed on a quarterly basis. The routine maintenance procedures must be performed by a qualified BIOMEDICAL ENGINEER or MAINTENANCE ENGINEER.

For further information regarding the qualifications for performing the maintenance procedures, or to address questions regarding the procedure, contact Custom Ultrasonics, 215-364-1477.

To Begin Maintenance Procedure:

1. Turn the hot and cold water valves OFF using either the shut off valves or the faucet handles. Start the system in a wash cycle to relieve the water pressure. Be sure to note the settings of the VALVES, and return the VALVES to the same setting at the completion of the Maintenance Procedure
2. Turn the system off by moving the CIRCUIT BEAKER to the "OFF" position on both the computer module and the System.
3. Disconnect the AC plug(s) from the wall receptacle(s).
4. Remove the front panel(s) by removing the screw at the lower center of the white panel(s).
5. Move the System(s) away from the wall.
6. Remove the rear panel(s) by turning the screw(s) at the perimeter of the white panel(s).
7. Inspect interior of the system for visible liquid leakage. If leakage is apparent, locate the source of the leak(s) and repair.
8. Disconnect the hot and cold water line(s) from the System. Check filter screens and hoses for wear. Replace as needed. After inspection, reconnect to the System. DO NOT TURN ON THE WATER VALVES YET.

9. Clean all the solenoid housings and diaphragms per instructions in the BIOMEDICAL MANUAL:
 - a. H/L/D Feed Solenoid
 - b. H/L/D Return Solenoid
 - c. Drain Solenoid
 - d. Residual Drain Solenoid
 - e. Water Inlet Solenoid
 - f. Hand Spray Solenoid
 - g. Air Solenoid
 - h. Detergent Solenoid
10. Remove the four (4) wing nuts from the drain pump(s) and chemical pump(s). Inspect impellers for foreign objects. Clean and reassemble. Be certain that the wing nuts are secure.
11. Check all the compression fittings for the purge pump(s), residual drain, and air pump(s) and detergent pump.
12. Check hand spray tubing, handle and fittings for leakage and wear.
13. Check plumbing unions in the chemical feed, return, and drain lines.
14. Check purge pump(s) to the counter top manifold(s) to insure coil is secure (see BIOMEDICAL MANUAL).
15. Check military connector to ultrasonic generator(s) from transducers on the bottom of the ultrasonic chamber(s). Check the ground lug on the transducer plate(s) located next to the gray shielded cable to the generator(s).
16. Clean the front and rear louvers of the generator enclosure(s).
17. The interface is located below the shelf on the right side of the cabinet. Check and secure all four (4) plugs.
18. Check the drain and residual drain hoses for wear at the site of the standpipe.
19. Check the movement of the circuit breaker and inspect the hospital grade plug(s).
20. Two floats are located behind the metal cover in the scope processing chamber(s). Check and clean the shafts of the floats.

21. Locate the float in the chemical reservoir(s). Check and clean the shaft of the float.
22. At the lower rear of the scope processing chamber(s), locate and remove the filter screen from behind its housing and clean. Replace screen in the housing and ensure the screen is fully secured behind and within the housing.
23. Reconnect the System(s) AC plug(s) to the wall receptacle(s).
24. Replace any water filters before turning machine back on (Refer to Filter change section in the Bio-med manual). Turn "ON" the hot and cold water faucet(s) and reset the valves to their original positions.
25. Connect the AC plug(s) from the computer and the System into the wall receptacle(s), and engage the CIRCUIT BREAKERS.
26. Turn the computer "ON".
27. Remove the hand spray from its holder or insert the hand spray into the bulkhead, dependent on your System, and turn "ON" the rinse SWITCH (on the control panel). Fill the chemical reservoir(s) to a level above the LOW LEVEL MARK located on the wall of the chamber(s) (disregard the digital readout on the control panel).
28. Beginning from the top, insert any three (3) endoscope adapters.
29. Enter the STANDARD PROGRAM SCREEN and press F2, system data, in order to check the chemical time. Follow the screen prompt to return to STANDARD PROGRAM SCREEN.
30. Move all switches on the control panel, except the heater switch, to the "DOWN" position.
31. Measure water temperature, it should read around 110° Fahrenheit.
32. Press F8, "WASH & H/L/D". Run a complete wash/disinfect cycle and, at the same time, check for any liquid leakage.
33. At completion of the MAINTENANCE PROCEDURE, press F2, system data. Return the chemical period to its original setting.
34. Replace the front and rear panels.
35. Position the system into its original location making certain that all hoses are in position and that they are not kinked.

36. Confirm completion of the ROUTINE MAINTENANCE PROCEDURE to the department supervisor and document accordingly. Mail Routine maintenance cards to Custom Ultrasonics. Department staff may now refill the chemical reservoir(s) and start using machine.

NOTE: Every six (6) months, remove the sensor (resembles a spark plug) from the PVC tee which is located before the input of the drain pump(s). Clean and reassemble using Teflon tape. Do not over tighten and break PVC tee. Make certain that the low voltage line to the sensor and ground are secure.

Water Quality and Temperature

Across the nation, water quality varies and can affect the mechanical components of your System 83 Plus™, and/or the outcome of the STANDARDIZED PROCESS. The mineral and sediment content in your hospital water supply may leave deposits on the instrument(s) and/or the mechanical components of the System, and may interfere with the action of some detergents and germicide agents.

All potable tap water contains resident microbial contaminants that, under normal circumstances, are not of clinical concern. However, the water contaminant level should be assessed to determine its acceptability for processing medical devices.

Custom Ultrasonics requires installation of a twenty (20) inch, 5 micron filter assembly for the water lines supplying the system to remove sediment, and a 0.1 micron bacterial filter in tandem, following the 5 micron filter assembly. A 25 micron pre-sediment filter is recommended to be added in front of the 5 micron filter depending on water quality. *Contact Custom Ultrasonics for information on water filter systems.*

Water temperature is also critical to the process outcome, and should be set approximately around 110° Fahrenheit. Which is the temperature that is compatible with the flexible endoscope. In combination with a detergent formulated to dissolve organic contaminants within this temperature range, the warm water will potentiate the removal of contaminants during the cleaning phase of the STANDARDIZED decontamination process. The warm water enhances the separation of most soils, and it is the best vehicle for complete removal of contaminants, residual detergent, and chemical solutions during the rinsing phase of the process. The water temperature should never exceed 120 degrees Fahrenheit.

Mechanical Action During the System 83 Plus™ Cleaning Phase

Mechanical action, in combination with a detergent, is important during almost any cleaning process. System 83 Plus™ employs both mechanical oscillation (water pick effect in each channel) and sound waves to potentiate the activity of the detergent and the water during the cleaning phase of the STANDARDIZED PROCESS, and to assure removal of residues during the rinsing phases.

The *low intensity* sound waves of the System 83 Plus™ were chosen to meet the technical requirements of the endoscopic device(s) and because it enhanced thorough cleaning and rinsing. As the *low intensity* sound waves are delivered during the cleaning and rinsing solutions, molecules are set in very rapid motion and small bubbles develop. When these bubbles reach a critical mass, they implode, creating a vacuum that draws from adjacent cracks and crevices any small bits of foreign matter, including those hidden or inaccessible.

Oscillation of the cleaning, liquid germicide, and rinsing solutions through the internal channels of the device(s) at a rate of **sixty (60) times per second** (water pick effect) completes the mechanical action necessary for removal of contaminants and residues.

The frequency of the sound wave and the rate of oscillation is within acceptable parameters and meets the technical requirements of the endoscopic device(s).

Time Specification for the STANDARDIZED PROCESS:

Each phase of the STANDARDIZED PROCESS has been precisely timed to achieve optimal results based on the correct combination of water temperature, detergent, and chemical agent. *Contact Custom Ultrasonics for information on our cleaning and germicide data.*

The total cycle time of the STANDARDIZED PROCESS depends on the length of immersion time of the chemical, per the liquid sterilants label requirements.

Liquid Chemical Germicide ("LCG"):

There are several germicides available to chemically immerse your medical device(s). Custom Ultrasonics, as the manufacturer of System 83 Plus™, does not recommend a specific chemical germicide except as it may relate to the germicides compatibility with the System 83 Plus™ and endoscope(s). Contact Custom Ultrasonics to confirm compatibility of the germicide with your System 83 Plus™.

The STANDARDIZED PROCESS of System 83 Plus™

The STANDARDIZED PROCESS of System 83 Plus™ includes a chemical immersion phase during which the germicide is delivered to the processing chamber in order to completely immerse the device(s). The germicide circulates through the channels and around the device(s) per the recommendation of the chemical label.

Processing Accessories:

The accessory is an integral part of endoscopy. Because the accessory generally breaks a mucosal surface, it is considered a critical device, and it is a potential vector for cross infection; thus the requirements for processing the accessory are different than for the endoscope.

Because the spring like housing of some accessories may entrap contaminants between the shaft and the internal surface of the spring housing, access for cleaning by manual methods may be prevented. Use of a high intensity sound wave is recommended to assist in thoroughly cleaning the accessory.

If your System 83 Plus™ was purchased with an ultrasonic chamber, for accessories, they will be processed with a high intensity sound wave. This sound wave will force the detergent solution in the spring like housing to remove contaminants. The sound wave functions in the same manner during the rinsing, to remove any residual contaminants and detergent. Your accessories are now ready for steam autoclaving.

Physical Description of the System 83 Plus™

The System 83 Plus™ is a free standing endoscopy reprocessing unit that connects to an electrical wall receptacle(s), hot and cold water lines with in line sediment and bacteria filters, and waste (stand pipe) line(s). It is mounted on heavy duty casters for mobility, and for easy access to the internal mechanical and electronic components during routine maintenance procedures.

The cabinet is fabricated from carbon steel and painted; the counter top is solid PVC with an acrylic laminate that resists the corrosive properties of detergents and chemicals.

Removal of the cabinet's front and back access panels, reveal the plumbing lines, mechanical components, and the electronic assemblies. These panels should only be removed by a qualified technician.

The front door contains the operational switches for the air pump and the hand spray. A heating option for the chemical reservoir is available with all models of System 83 Plus™. The temperature of the chemical solution is displayed on the VGA color monitor.

The computer contains the hardware for implementing the software. Included is a keyboard, printer, and a high resolution color monitor that displays the components and phases performed by the software program.

A circuit breaker, mounted on the rear wall above the power cord, serves as the main power switch for the System 83 Plus™. The circuit breaker should remain in the "ON" position during use; it should be in the "OFF" position for maintenance. The on/off button on the computer inside the front door is used to power the machine on and off.

Installation and In-Service of the System 83 Plus™

Electrical Requirements:

The System 83 Plus™ requires DEDICATED 120 Volt, 15 amp 60 Hz 1Ph receptacle. GFCI receptacles are not recommended since the system contains an electrostatic isolation transformer to meet the requirements for leakage to ground as specified for a medical devices.

The number of DEDICATED electrical lines required is model dependent.

Mechanical Requirements:

The physical space requirements are model dependent. The appropriate "rough-in" requirements were provided with the Quotation for Purchase and are in the Bio-Medical manual.

Standard potable water, hot and cold, with ½" or ¾" copper lines, ¾" male garden hose adapters, and shut off valves are required; the number of water lines is model dependent. The required water pressure is between 30 to 50 psi. If the water pressure is to high pressure reducer valves must be installed to maintain 30 to 50 psi.

Five (5) micron water filters with 20" cartridges must be installed in the water lines so as not to interfere with the required water pressure of 30 to 50 psi. To achieve bacteria free water a (.1) micron filter must follow the five micron filter.

Water Temperature is required to be approximately 110° F. Water temperature should not exceed 120° F.

A standpipe drain two inches (2") in diameter and eighteen inches (18") from the floor is recommended for each system.

Computer Hardware:

An IBM Compatible CPU, Keyboard, High Resolution Color Monitor, and a Printer are supplied as part of the System 83PLUS™.

The keyboard has a protective cover that can be easily cleaned.

Parts Supplied with System 83 Plus™

The System is equipped with a standard hospital grade, grounded, power cord that is connected to the system's circuit breaker.

The computer is equipped with surge protection.

The System is equipped with standard 1/2" internal diameter copper water lines and 5/8" fill and drain hose. The residual drain hose is 1/2" and blue in color.

Based on your list of endoscopes received prior to In-service training, all required channel adapters are provided for device attachment to the System.

A hand spray is provided with the System to assist in the thorough cleaning of the processing chamber(s) and chemical reservoir(s) during the good housekeeping methods.

The Operator's and Bio-med Manual for your System 83 Plus™ and the computer assembly, describes the system operation, steps for problem solving, and the routine maintenance procedure.

Installation and In-service Program

All Systems are Installed and In-serviced by a company engineer at no extra cost. The engineer, will assure that all System functions are operational.

The In-service Program is dedicated to the Operator, Maintenance, and/or Biomedical Personnel; and is one day and a half in length.

During the In-service Program, all System operations, instrument adaptation and routine maintenance procedure will be demonstrated, as well as the System's diagnostics software service program.